



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,424	04/20/2001	David L. Brown	3364/1 (PHA 4176)	1761
7590 01/23/2004				
Pharmacia Corporation Corporate Patent Department P.O. Box 5110 Chicago, IL 60680-9889				
EXAMINER ROBINSON, BINTA M				
ART UNIT		PAPER NUMBER		
1625				
DATE MAILED: 01/23/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,424

Applicant(s)

BROWN ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-16, 31, 32, 35-38, 40, 41, 92, 94, 99, 101 and 105-113 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-16, 31-32, 35-38, 40, 41, 92, 94, 99, 101, 105-113 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

Detailed Action

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 11-16, 31-32, 35-38, 40, 41, 92, 94, 99, 101, 105-113 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the radicals A equal to all 5 or 6 membered partially saturated or unsaturated heterocyclic rings, R3 equal to heterocyclyl, heterocyclyloxy, or heterocyclyl C1-3 alkyl rings. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the

Art Unit: 1625

invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims

The breadth of the instant claims is seen to encompass compounds of formula I where A can equal 5- or 6- saturated or unsaturated heterocyclyl membered ring and R3 equal to heterocyclyl, heterocyclyloxy, or heterocyclyl C1-3 alkyl rings. However, the applicant does not exemplify compounds of formula I where these heterocyclyl rings can be other than imidazole, oxazolone, isooxazole, furanyl, pyrazole, pyridinyl, or oxazole. Applicant has not enabled preparation and use of derivatives to support the breadth of claims which include radicals A and R3 of the compound of formula are 5-6 membered partially saturated or unsaturated heterocyclic rings, heterocyclyloxy, or heterocyclyl C1-3 alkyl rings other than imidazole, oxazolone, isooxazole, furanyl, pyrazole, pyridinyl, or oxazole. Despite references in the specification regarding compounds that can be made, there is little enabling disclosure of particular compounds other than those where R3 and R4 are imidazole, oxazolone, isooxazole, furanyl, pyraozole, pyridinyl, or oxazole that can be made. Details for making a few compounds, which do not include compounds of formula I where R3 and R4 are imidazole, oxazolone, isooxazole, furanyl, pyraozole, pyridinyl, or oxazole, represents inadequate support for claims encompassing compounds of formula where A can equal 5- or 6-

saturated or unsaturated heterocyclyl membered ring and R3 equal to heterocyclyl, heterocycloxy, or heterocyclyl C1-3 alkyl rings. Applicant has taught how to make and use only a few compounds and is therefore not entitled to claim all of them.

The nature of the invention

The nature of the invention is to use the instant compounds to treat cyclooxygenase-mediated disorders.

The level of one of ordinary skill

The level of skill is that of a MD or PhD.

The level of predictability in the art

There does not appear to be an adequate disclosure of structural chemical formulas for the breadth of compounds claimed that show that the applicant has made the claimed invention. There is not seen sufficient evidence to extrapolate from the limited disclosure that there is a sufficient description to encompass compounds embraced by the claimed chemical core. The skilled artisan in this field would not correlate the variability in structure to analogous or predictable function because the state of this art does not provide a basis or guidance to make such assumptions.

The amount of direction provided by the inventor

The inventor does not provide sufficient evidence as to how to make and use compounds of formula I where these compounds are those where A and R3 can be heterocyclyl rings other than imidazole, oxazolone, isooxazole, furanyl, pyraozole,

Art Unit: 1625

pyridinyl, or oxazole.

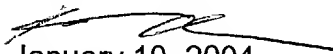
In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson



January 10, 2004